



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/088,866

07/02/2002

Michael Schirner

SCH 1869

6769

23599

7590

09/12/2008

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

2200 CLARENDON BLVD.

SUITE 1400

ARLINGTON, VA 22201

EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

09/12/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/088,866

**Applicant(s)**

SCHIRNER ET AL.

**Examiner**

Sheela J. Huff

**Art Unit**

1643

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date 1/8/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

***Response to Amendment***

The amendment filed on 6/2/08 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 15-35 are pending.

The rejections under 35 USC 102b are withdrawn in view of applicant's arguments.

***Information Disclosure Statement***

The information disclosure statement filed 1/8/08 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because reference C59 and C86 do not contain proper citations as required by 37 CFR 1.98(b). All reference except for these two have been considered.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

Claims 16, 18, 20, 22, 27-33 and 35 remain/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 18, 20, 22 and 27-33 were inadvertently omitted from the previous office action. Claim 35 is added because of its recitation of L19. The reasons for this rejection are of record in the paper mailed 2/1/06.

Applicant argues that L19 is a single chain antibody and cites Neri et al 2003/0045681 to show how to prepare this single chain antibody. It is not clear from applicant's specification that L19 is a single chain. (applicant does not mention E1, but it is assumed that applicant is also arguing E1 since it is part of the rejection.) The specification as originally filed refers to L19 and E1 from the Viti et al reference. This reference states on page 347, col. 2, first paragraph under "Material and Methods" that the "isolation of the E1 and L19 Abs has been as previously described(18)". This reference refers to E1 and L19 and antibodies NOT single chains. In fact, looking at the footnote on page 347, the reference clearly distinguishes between "Ab" and "scFv". "Ab" means antibody and "scFv" means single chain. Thus, this reference states that L19 and E1 are antibodies NOT single chains. Furthermore, "(18)" refers to Pini et al and this reference discloses the production of the single chains and this reference states that single chains were products by PCR assembly (page 21770, first column). Production of the single chains by PCR involves obtaining primers from the original antibody and in this case the original antibody would be E1 or L19. While Pini et al in Table II do refer to a few amino acid residues, this is not the entire VH or VL which is what the single chain would be made of. Thus, from these references it appears that there are antibodies designated E1 or L19. A fair reading of applicant's specification would not lead one of skill in the art to know that L19 and E1 and the prior art cited by applicant are single chains. **Applicant is cautioned against the addition of new matter into the specification.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Neri et al Nature Biotechnology Vol. 15 p. 1271 (11/97) or Neri et al US 2003/0045681 (filed 5/11/98) in view of Viti et al Cancer Research vol. 59 p. 347 (1/99), applicant's admission in the sentence bridging pages 7-8 of the specification and Licha et al US 6083485 (filed 11/7/97). The reasons for this rejection are of record in the paper mailed 11/27/07.

Applicant argues that the "A" in the declaration is the same antibody and is L19. This needs to part of the declaration. However, the declaration is still deficient for the other reasons cited.

Applicant argues that the Licha references do not show a direct comparison to prove their statement of "highly sensitive signals" nor does Viti reference show an increased affinity.. First of all, these are assertions and if applicant has any objective evidence to support these assertions then applicant is invited to show that the statements are inaccurate. Second, the Licha reference does clearly state that the increased fluorescent intensity is compared to a similarly dosed porphyrin (col. 9, lines 25-28).

Claims 15-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Neri et al Nature Biotechnology Vol. 15 p. 1271 (11/97) or Neri et al US

2003/0045681 (filed 5/11/98) in view of Viti et al Cancer Research vol. 59 p. 347 (1/99), applicant's admission in the sentence bridging pages 7-8 of the specification and Licha et al US 6083485 (filed 11/7/97) and Licha et al 6630570 (filed 4/12/99). The reasons for this rejection are of record in the paper mailed 6/22/06. The reasons for this rejection are of record in the paper mailed 11/27/07.

Applicant's arguments have been addressed above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-

0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/  
Primary Examiner  
Art Unit 1643

sjh